4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 101, 106, 170, 172, 173, 184, and 190

[Docket No. FDA-2022-N-2898]

Food Labeling, Infant Formula Requirements, Food Additives and Generally Recognized as Safe Substances, New Dietary Ingredient Notification; Technical Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA or we) is amending its regulations that pertain to food labeling, infant formula requirements, food additives, direct food substances affirmed as generally recognized as safe (GRAS), and new dietary ingredient (NDI) notifications. These amendments correct typographical errors, correct errors in sample labels, restore inadvertent omissions, and update office and organization names, addresses, and other references. This action is ministerial or editorial in nature.

DATES: This rule is effective on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: *For further information about food labeling amendments*, Mark Kantor, Office of Nutrition and Food Labeling (HFS-830), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1450.

For further information about infant formula amendments, Carrie Assar, Office of Nutrition and Food Labeling (HFS-850), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1450.

For further information about food additive and GRAS amendments, Annette McCarthy, Office of Food Additive Safety (HFS-205), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1200.

For further information about NDI notification amendments, Laura Rich, Office of Dietary Supplement Programs (HFS-810), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-8152.

For further information about the rule, Alexandra Jurewitz, Office of Regulations and Policy (HFS-024), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

SUPPLEMENTARY INFORMATION:

I. Background

A. Food Labeling (21 CFR Part 101)

In the *Federal Register* of May 27, 2016 (81 FR 33742), we published a final rule entitled "Food Labeling: Revision of the Nutrition and Supplement Facts Labels" (the Nutrition Facts Label Final Rule). The Nutrition Facts Label Final Rule amended our labeling regulations for conventional foods and dietary supplements to provide updated nutrition information on the label to assist consumers in maintaining healthy dietary practices.

In the *Federal Register* of December 21, 2018 (83 FR 65493), we issued a technical amendment pertaining to the Nutrition Facts label requirements. The technical amendments corrected errors that were made in sample labels, restored incorrect deletions, corrected the edition of a reference cited in the Nutrition Facts Label Final Rule, and corrected cross-references to other regulations. However, certain errors remained, and so this rulemaking will provide additional corrections to sample labels and updates to office names.

B. Notification of An Adulterated or Misbranded Infant Formula (§ 106.150 (21 CFR 106.150))

In the *Federal Register* of February 10, 2014 (79 FR 7934), FDA published an interim final rule entitled "Current Good Manufacturing Practices, Quality Control Procedures, Quality

Factors, Notification Requirements, and Records and Reports, for Infant Formula" (2014 interim final rule). In the *Federal Register* of June 10, 2014 (79 FR 33057), FDA issued a final rule, adopting, with some modifications, the 2014 interim final rule where FDA established notification requirements for adulterated or misbranded infant formula. The 2014 interim final rule included an incorrect statutory citation in this provision, and so this rulemaking is intended to correct the citation.

C. Food Additives and GRAS Substances (21 CFR Parts 170, 172, 173, and 184)

Our regulations in parts 170, 172, 173, and 184 (21 CFR parts 170, 172, 173, and 184) discuss the general principles for evaluating food additive safety, the use of food additives, and substances affirmed as GRAS. Our regulations reference office names and addresses that are no longer correct, reference an organization's name that is no longer correct, and include a potentially confusing reference to the Federal Food, Drug, and Cosmetic Act (FD&C Act); consequently, this rulemaking will update names and addresses and clarify a reference to the FD&C Act.

D. Dietary Supplements (21 CFR Part 190)

In the *Federal Register* of September 23, 1997 (62 FR 49886), FDA published a final rule entitled "Premarket Notification for a New Dietary Ingredient." The final rule specifies the information a manufacturer or distributor must include in its premarket NDI notification and establishes the administrative procedures for these notifications. The regulation refers to an FDA office name and address that is no longer correct, and so this rulemaking will update the office name and address.

II. Description of the Technical Amendments

We are making technical amendments to our regulations in parts 101, 106, and 190 (21 CFR parts 101, 106, and 190) and parts 170, 172, 173, and 184. In general, part 101 pertains to food labeling, including the nutrition labeling of food. Part 106 pertains to current good manufacturing practice, quality control procedures, quality factors, records and reports, and

notifications regarding infant formula. Part 170 pertains to food additives while part 172 pertains to food additives permitted for direct addition to food for human consumption. Part 173 pertains to secondary food additives permitted in food for human consumption. Part 184 pertains to direct food substances affirmed as generally recognized as safe. Part 190 pertains to dietary supplements.

A. Food Labeling (Part 101)

Since we published the technical amendments to the final rule in the *Federal Register*, we have become aware of additional changes or corrections that are needed to the Nutrition Facts label requirements. These changes or corrections are non-substantive; for example, § 101.9(d)(11) and (j)(5)(ii)(B) (21 CFR 101.9(d)(11) and (j)(5)(ii)(B)) show sample Nutrition Facts labels. In one case, the sample label included an extra word in the phrasing of a nutrient declaration. In the other case, the sample label included a number that did not comply with the rounding requirements for certain nutrients. The technical amendment revises the sample labels. We describe these and other changes to the Food Labeling regulations below.

1. Section 101.4 and Office Name Corrections

Our regulations in 21 CFR 101.4 discuss the designation of food ingredients and state that certain references are available for examination at the "Food and Drug Administration's Main Library." The technical amendment revises where the references are available for examination to be FDA's Dockets Management Staff.

2. Section 101.9(b)(7)(vi) and Addresses for Obtaining Reference Materials

The Nutrition Facts Label Final Rule revised the name of the program office that is responsible for developing regulations and answering questions related to nutrition labeling, as well as for maintaining some references discussed throughout § 101.9. The program office's former name was the Office of Nutritional Products, Labeling and Dietary Supplements, and the Nutrition Facts Label Final Rule changed the program office's name to the Office of Nutrition and Food Labeling. However, our regulations in § 101.9(b)(7)(vi) continued to use the program

office's former name. Therefore, this technical amendment revises § 101.9(b)(7)(vi) by replacing "Office of Nutritional Products, Labeling and Dietary Supplements" with "Office of Nutrition and Food Labeling."

3. Section 101.9(c)(8)(iv) and Units of Measure

Our regulations in § 101.9(c)(8)(iv) provide the Reference Daily Intakes (RDIs), nomenclature, and units of measure for various vitamins and minerals that are essential in human nutrition. The regulation lists the vitamins and minerals in a table, and footnotes to the table provide additional information. Footnote 3 discusses the units of measure that may be used for vitamin A. The footnote says, in part, that the abbreviation "RAE" stands for "Retinol activity equivalents" and that 1 microgram RAE equals 1 microgram retinol, "2 microgram supplemental β-carotene" or "dietary 24 micrograms dietary β-cryptoxanthin." The technical amendment replaces "2 microgram" with "2 micrograms" and deletes the word "dietary" before "24 micrograms."

4. Section 101.9(d)(11)(iii) and the Tabular Format Label Illustration

Our regulations in § 101.9(d)(11)(iii) contain a sample Nutrition Facts label in a tabular format. However, the sample label contains the statement "Includes 1g of Added Sugars." Under § 101.9(c)(6)(iii), however, the correct statement is "Includes 'X' g Added Sugars." Therefore, the technical amendment revises the sample label by removing the word "of" so that the statement reads "Includes 1g Added Sugars."

5. Section 101.9(j)(5)(ii)(B) and "Infants through 12 Months of Age" Label Illustration

Our regulations in § 101.9(j)(5)(ii)(B) contain a sample Nutrition Facts label for a food intended for infants through 12 months of age. The sample label declares the amount of sodium to be 74 mg. Under § 101.9(c)(4), however, the amount of sodium declared on a Nutrition Facts label must be expressed to the nearest 5-milligram increment when the serving contains 5 to 140 milligrams of sodium. Therefore, the technical amendment provides a revised sample label correcting the amount of sodium from "74mg" to "75mg."

6. Section 101.9(j)(13)(i)(B), Footnote Requirements for Foods in Small Packages, and Minimum Type Size

Our regulations in § 101.9(j)(13)(i)(B) discuss requirements for foods in small packages. The Nutrition Facts Label Final Rule revised § 101.9(j)(13)(i)(B) so that the Nutrition Facts label on small packages would not be required to bear a footnote explaining what the "% Daily Value" means and manufacturers could voluntarily include an abbreviated footnote of "% DV = % Daily Value" in a type size no smaller than 6 point. Additionally, these requirements include, among other things, the minimum type size for required information. The minimum type size is specified as "no smaller than 6 point or all upper-case type of 1-16 inches."

The inclusion of the alternate footnote option was inadvertently omitted when changes to the same paragraph, as described in the *Federal Register* of December 1, 2014 (79 FR 71259), became effective on December 1, 2016. Consequently, we are restoring the alternate footnote option. The technical amendment also corrects the minimum type size, in inches, to "1/16 inches" rather than "1-16 inches."

7. Section 101.9(j)(13)(ii)(A)(*1*) and Tabular Display for Small Packages Label Illustration

Our regulations in § 101.9(j)(13)(ii)(A)(*1*) provide a sample label for the tabular display for small packages. The sample label included an asterisk (*) after the "% DV" heading but omitted any footnote or other explanation as to what the asterisk was referring. The sample label also included "servings per container" and "serving size" declarations that are not consistent with our rounding regulations in § 101.9(b)(5)(i), which state that "Cups shall be expressed in 1/4- or 1/3-cup increments."

Manufacturers may voluntarily include an abbreviated footnote "% DV = % Daily Value" for products in small packages, but because the sample label did not include the abbreviated footnote, the technical amendment removes the asterisk after the "% DV" heading in the sample label. The technical amendment also revises the serving size from "1/6 cup" to "1/3 cup" and the

servings per container from “5 servings per container” to “about 3 servings per container” in the sample label.

8. Section 101.9(j)(13)(ii)(A)(*2*) and Linear Display for Small Packages Label Illustration

Our regulations in § 101.9(j)(13)(ii)(A)(*2*) provide a sample label for the linear display for small packages. The sample label included a “% DV” declaration of “Potas. (5% DV).” Under § 101.9(c)(8)(iii), however, the “% DV” for vitamins and minerals must be expressed to the nearest 2-percent increment up to and including the 10-percent level. Therefore, the technical amendment changes “Potas. (5% DV)” to “Potas. (6% DV)” in the sample label.

9. Section 101.9(j)(13)(ii)(B) and Corrections to Abbreviation Instructions

Our regulations in § 101.9(j)(13)(ii)(B) allow for the use of “Vit.” and “Potas.” as abbreviations for “Vitamin” and “Potassium,” respectively, on the labels of small and intermediate-sized packages. While our regulations in § 101.9(d)(12) also show the use of these abbreviations on the standard vertical side-by-side label illustration, indicating that we intended to permit this use, we failed to state explicitly that these abbreviations are permitted on labels other than the labels of small and intermediate-sized packages. In addition, the regulations allow for the use of “Total carb.” as an abbreviation for “Total carbohydrate” on dual-column displays and refers to other requirements in § 101.9 by their paragraph designations.

The technical amendment revises § 101.9(j)(13)(ii)(B) to clearly state that the use of “Vit.” and “Potas.” as abbreviations for “Vitamin” and “Potassium,” respectively, on the standard vertical side-by-side label display as shown in § 101.9(d)(12), is permitted in addition to their use on the labels of small and intermediate-sized packages. The technical amendment also revises § 101.9(j)(13)(ii)(B) to include “of this section” at the end of the sentence pertaining to “Total carbohydrate” so that it refers to “paragraphs (e)(5), (e)(6)(i), and (e)(6)(ii) of this section.”

10. Section 101.45 and Office Name Correction

Our regulations in 21 CFR 101.45 discuss the guidelines for voluntary nutrition labeling of raw fruits, vegetables, and fish and encourages submission of nutrient databases to the "Office of Nutritional Products, Labeling and Dietary Supplements (HFS-800)." The regulations also state that guidance is available from the "FDA Office of Food Labeling." The technical amendment revises the office name to be "Office of Nutrition and Food Labeling (HFS-800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740."

11. Section 101.80 and Office Name Correction

Our regulations in 21 CFR 101.80 discuss dietary noncariogenic carbohydrate sweeteners and dental caries health claims. The regulations state that a reference is available for examination at the "Food and Drug Administration's Main Library." The technical amendment revises where the reference is available for examination to be FDA's Dockets Management Staff.

12. Section 101.81 and Office Name Correction

Our regulations in 21 CFR 101.81 discuss soluble fiber from certain foods and risk of coronary heart disease health claims. The regulations state that certain references are available for examination at the "Food and Drug Administration's Main Library." The technical amendment revises where the references are available for examination to be FDA's Dockets Management Staff.

13. Section 101.83 and Office Name Correction

Our regulations in 21 CFR 101.83 discuss plant sterol/stanol esters and risk of coronary heart disease health claims. The regulations state that certain references are available for examination at the "Food and Drug Administration's Main Library." The technical amendment revises where the references are available for examination to be FDA's Dockets Management Staff.

14. Section 101.93 and Office Name Correction

Our regulations in part 101, subpart F, discuss specific requirements for descriptive claims that are neither nutrient content claims nor health claims. In 21 CFR 101.93 the requirements for notifications for certain types of statements for dietary supplements are discussed and submissions are directed to the "Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740." The technical amendment revises the office name to be "Office of Dietary Supplement Programs (HFS-810)," which reflects the office's current name.

15. Section 101.108 and Office Name Correction

Our regulations in 21 CFR 101.108 discuss temporary exemptions for purposes of conducting authorized food labeling experiments. The regulation states that written proposals should be sent to the "Division of Dockets Management (HFA-305)." The technical amendment revises the office name to be "Dockets Management Staff (HFA-305)."

B. Notification of an Adulterated or Misbranded Infant Formula (§ 106.150)

Our regulations in § 106.150(a)(1) state that a manufacturer must promptly notify us when the manufacturer has knowledge that reasonably supports the conclusion that an infant formula processed by that manufacturer and that has left an establishment controlled by the manufacturer may not provide the nutrients required by section 412(i) of the FD&C Act. The regulation was intended to provide a corresponding U.S. Code cite for section 412(i) of the FD&C Act and identifies the U.S. Code cite as 21 U.S.C. 350d(i). The U.S. Code citation should have been 21 U.S.C. 350a(i). Therefore, the technical amendment replaces "21 U.S.C 350d(i)" with "21 U.S.C. 350a(i)."

C. Food Additives (Parts 170, 172, 173, and 184)

1. Sections 170.35, 170.38, and 170.39--Office Name Correction and Correction Regarding Dockets Management

The regulations in §§ 170.35(b)(1) and (b)(2), 170.38(b)(1) and (b)(2), and 170.39(e) and (g) (21 CFR 170.35(b)(1) and (b)(2), 170.38(b)(1) and (b)(2), and 170.39(e) and (g)) state that data, information, comments, or other documents are on display or available at the "Division of Dockets Management." The technical amendment revises these regulations to replace "Division of Dockets Management" with "Dockets Management Staff" to reflect the office's current name.

Similarly, our regulations in § 170.39(d), (e), and (h) refer to the "Office of Premarket Approval." The technical amendment replaces "Office of Premarket Approval" with "Office of Food Additive Safety" to reflect the office's current name.

2. Sections 172.105, 172.133, 172.250, 172.859, 172.878, and 172.882--Office Name and Contact Information Correction

Our regulations in 21 CFR 172.105, 172.133, 172.250, 172.859, 172.878, and 172.882 discuss the use of anoxomer, dimethyl carbonate, petroleum naphtha, sucrose fatty acid esters, white mineral oil, and synthetic isoparaffinic petroleum hydrocarbons as food additives, respectively, and state that certain references are available from the "Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740." The technical amendment replaces all instances of "Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740" with "Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1200." We are making this change to include the name and contact information of the office where the references are available.

3. Section 172.155--Office Name, Contact Information, and Other Minor Corrections

Our regulations in 21 CFR 172.155 discuss the use of natamycin (also known as pimaricin) as a food additive. Section 172.155(c) states that a reference is available from the "Division of Product Policy (HFS-206)" and provides the office's address. The regulation also states that this reference is available for examination at the "Food and Drug Administration's

Main Library." The technical amendment: (1) updates the associated address of where the reference is available to be "Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1200;" and (2) revises where the reference is available for examination to be FDA's Dockets Management Staff.

4. Sections 172.167, 172.185, 172.320, 172.345, 172.379, 172.380, 172.665, 172.712, 172.780, 172.810, 172.812, 172.831, 172.841, 172.862, and 172.867--Office Name and Contact Information Corrections

Our regulations in 21 CFR 172.167, 172.185, 172.320, 172.345, 172.379, 172.380, 172.665, 172.712, 172.780, 172.810, 172.812, 172.831, 172.841, 172.862, and 172.867 discuss the use of silver nitrate and hydrogen peroxide solution, TBHQ, amino acids, folic acid (folacin), vitamin D_2, vitamin D_3, gellan gum, 1,3-butylene glycol, acacia (gum arabic), dioctyl sodium sulfosuccinate, glycine, sucralose, polydextrose, oleic acid derived from tall oil fatty acids, and olestra as food additives, respectively. The regulations state that certain references are available for examination at the "Food and Drug Administration's Main Library." The technical amendment revises where the references are available for examination to be FDA's Dockets Management Staff.

5. Sections 172.723--Office Contact Information and Other Minor Corrections

Our regulations in 21 CFR 172.723 discuss the use of epoxidized soybean oil as a food additive. The regulations state that certain references may be examined at either the "Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1200" or the "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039." The technical amendment revises where the references are available for examination to be FDA's Docket Management Staff.

6. Sections 172.736, 172.803, and 172.869--Office Contact Information and Other Minor Corrections

Our regulations in 21 CFR 172.736, 172.803, and 172.869 discuss the use of glycerides and polyglycides of hydrogenated vegetable oils, advantame, and sucrose oligoesters as food additives, respectively. The regulations state that certain references are available from either the "Office of Food Additive Safety, 5001 Campus Dr., College Park, MD 20740," the "Office of Food Additive Safety, Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740," or the "Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, 5001 Campus Dr., College Park, MD 20740" and are available for examination at the "Food and Drug Administration's Main Library." The technical amendment: (1) updates the associated address of where the references are available to be the "Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1200;" and (2) revises where the references are available for examination to be FDA's Dockets Management Staff.

7. Sections 172.785, 172.809, 172.829, and 172.833--Office Contact Information and Other Minor Corrections

Our regulations in 21 CFR 172.785, 172.809, 172.829, and 172.833 discuss the use of *Listeria*-specific bacteriophage preparation, curdlan, neotame, and sucrose acetate isobutyrate as food additives, respectively. The regulations state that specific references are available from either the "Office of Food Additive Safety (HFS-200), Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039," the "Office of Food Additive Safety (HFS-200), Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993," or the "Office of Food Additive Safety (HFS-200), Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039,

240-402-1200" and are available for examination at the "Center for Food Safety and Applied Nutrition's Library" or the "Food and Drug Administration's Main Library." The technical amendment: (1) updates the associated address of where the references are available to be "Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1200;" and (2) revises where the references are available for examination to be FDA's Dockets Management Staff.

8. Sections 172.800 and 172.886--Office Name, Contact Information, and Other Minor Corrections

Our regulations in 21 CFR 172.800 and 172.886 discuss the use of acesulfame potassium and petroleum wax as food additives, respectively. The regulations state that certain references are available from the "Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740" and are available for examination at the "Food and Drug Administration's Main Library." The technical amendment: (1) updates the associated address of where the references are available to be "Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1200;" and (2) revises where the references are available for examination to be FDA's Dockets Management Staff.

9. Section 172.804--Office Name and Other Minor Corrections

Our regulations in 21 CFR 172.804 discuss the use of aspartame as a food additive. The regulations discuss standards of identity established under "section 401 of the act" and, at paragraph (c)(2), states that a specific analytical method is available from the "Office of Premarket Approval (HFS-200), Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993" and are available for inspection at either the "Center for Food Safety and Applied Nutrition's Library" or the "Food and Drug Administration's Main Library." The technical amendment: (1) revises "section 401 of

the act" to read as "section 401 of the Federal Food, Drug, and Cosmetic Act" to clarify which statute is being referenced; (2) replaces "Office of Premarket Approval" with "Office of Food Additive Safety" to reflect the office's current name; (3) updates the associated address for the Office of Food Additive Safety; and (4) revises where the reference is available for examination to be FDA's Dockets Management Staff.

10. Section 172.864--Office Name and Contact Information Corrections

Our regulations in 21 CFR 172.864 discuss the use of synthetic fatty alcohols as a food additive. The regulation states that various analytical methods are either available from the "Office of Food Additive Safety, 5001 Campus Dr., College Park, MD 20740" or the "Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740." The regulation also states that these references are available for examination at the "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039."The technical amendment: (1) replaces "Office of Food Additive Safety, 5001 Campus Dr., College Park, MD 20740" with "Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1200;" (2) replaces "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039" with "Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday;" and (3) replaces "Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740" with "Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1200." We are making this change to update the office address and contact information of the office where the references are available.

11. Sections 173.25, 173.45, 173.228, 173.280, 173.310, 173.325, 173.356, 173.368, and 173.375--Office Name and Contact Information Corrections

Our regulations in 21 CFR 173.25, 173.45, 173.228, 173.280, 173.310, 173.325, 173.356, 173.368, and 173.375 discuss the use of ion-exchange resins, polymaleic acid and its sodium salt, ethyl acetate, solvent extraction process for citric acid, boiler water additives, acidified sodium chlorite solutions, hydrogen peroxide, ozone, and cetylpyridinium chloride as secondary direct food additives, respectively, and state that certain references are available for examination from the "Food and Drug Administration's Main Library." The technical amendment revises where the references are available for examination to be FDA's Dockets Management Staff.

12. Sections 173.60, 173.65, 173.73, and 173.400--Office Name and Contact Information Correction

Our regulations in 21 CFR 173.60, 173.65, 173.73, and 173.400 discuss the use of dimethylamine-epichlorohydrin copolymer, divinylbenzene copolymer, sodium polyacrylate, and dimethyldialkylammonium chloride as secondary direct food additives, respectively, and state that certain references are available from either the "Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740" or the "Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740." The technical amendment replaces all instances of "Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740" or "Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740" with "Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1200." We are making this change to update the name and contact information of the office where the references are available.

13. Section 173.115--Office Contact Information Correction

Our regulations in 21 CFR 173.115 discuss the use of alpha-acetolactate decarboxylase (α-ALDC) enzyme preparation derived from a recombinant *Bacillus subtilis* as a secondary direct food additive. The regulations state that certain references may be examined at the "Center for Food Safety and Applied Nutrition, 5001 Campus Dr., College Park, MD 20740." The technical amendment revises where the references are available for examination to be FDA's Docket Management Staff.

14. Sections 173.160 and 173.165--Office Name, Contact Information, and Other Minor Corrections

Our regulations in 21 CFR 173.160 and 173.165 discuss the use of *Candida guilliermondii* and *Candida lipolytica* as secondary direct food additives, respectively, and state that certain references are available from the "Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740" and are available for examination at the "Food and Drug Administration's Main Library." The technical amendment: (1) updates the associated address of where the references are available to be "Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1200;" and (2) revises where the references are available for examination to be FDA's Dockets Management Staff.

15. Sections 173.300, 173.340, and 173.357--Office Contact Information and Other Minor Corrections

Our regulations in 21 CFR 173.300, 173.340, and 173.357 discuss the use of chlorine dioxide, defoaming agents, and materials used as fixing agents in the immobilization of enzyme preparations as secondary direct food additives, respectively, and state that certain references are available from the "Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740." The regulations also state that the references are available for examination at the "Food and Drug

Administration's Main Library." The technical amendment: (1) revises the office contact information to add the office's telephone number, "240-402-1200," to the end; and (2) revises where the references are available for examination to be FDA's Dockets Management Staff.

16. Section 173.370--Office Name, Contact Information, and Other Minor Corrections

Our regulations in 21 CFR 173,370 discuss the use of peroxyacids as secondary direct food additives. The regulation in § 173.370(c) states that specific analytical methods can be obtained from the "Division of Petition Review" or are available for examination at the "Food and Drug Administration's Main Library." The technical amendment: (1) updates the associated address of where the analytical methods can be obtained to be the "Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1200;" and (2) revises where the analytical methods are available for examination to be FDA's Dockets Management Staff.

17. Part 184--Office Name and Contact Information Corrections

Our regulations in part 184 discuss direct food substances affirmed as generally recognized as safe. Throughout part 184, the regulations state that certain references are available for examination at the "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039." The technical amendment revises where the references are available for examination to be "Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday."

18. Section 184.1538--Office Name Correction

Our regulations in § 184.1538 (21 CFR 184.1538) discuss nisin preparation as a specific substance affirmed as GRAS. The regulation in § 184.1538(b) and (d) states that copies of a specific reference are available from the "Division of Dockets Management." The technical amendment replaces "Division of Dockets Management" with "Dockets Management Staff" to

reflect the current name and contact information of the office from which the reference is available.

D. Dietary Supplements (Part 190)

Our regulations in part 190, subpart B, discuss NDI notifications. The regulation in 21 CFR 190.6(a) discusses the requirement for premarket notification and directs submissions to the "Office of Nutritional Products, Labeling and Dietary Supplements (HFS-820), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740." The technical amendment updates the address to "Office of Dietary Supplement Programs (HFS-810), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740." This technical amendment reflects our current organizational structure with regard to dietary supplements.

III. The Administrative Procedure Act

Publication of this document constitutes final action of these changes under the Administrative Procedure Act (APA) (5 U.S.C. 553). Under 5 U.S.C. 553(b)(3)(B) of the APA, an Agency may, for good cause, find (and incorporate the finding and a brief statement of reasons in the rules issued) that notice and public comment procedure on a rule is impracticable, unnecessary, or contrary to the public interest. We have determined that notice and public comment are unnecessary because these amendments only make technical or non-substantive changes, such as correcting sample labels, updating office or organization names, and updating addresses. For these reasons, we have determined that publishing a notice of proposed rulemaking and providing opportunity for public comment is unnecessary.

In addition, FDA finds good cause for these amendments to become effective on the date of publication of this action. The APA allows an effective date less than 30 days after publication as provided by an Agency for good cause found and published with the rule (5 U.S.C. 553(d)(3)). A delayed effective date is unnecessary in this case because the amendments do not impose any new regulatory requirements on affected parties. As a result, affected parties

do not need time to prepare before the rule takes effect. Therefore, we find good cause for this correction to become effective on the date of publication of this action.

IV. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

V. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VII. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive Order and, consequently, a tribal summary impact statement is not required.

List of Subjects

21 CFR Part 101

Food Labeling, Nutrition, Reporting and recordkeeping requirements.

21 CFR Part 106

Food grades and standards, Infants and children, Nutrition, Reporting and recordkeeping requirements.

21 CFR Part 170

Administrative practice and procedure, Food additives, Reporting and recordkeeping requirements.

21 CFR Parts 172 and 190

Food additives, Reporting and recordkeeping requirements.

21 CFR Parts 173 and 184

Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 101, 106, 170, 172, 173, 184, and 190 are amended as follows:

PART 101--FOOD LABELING

1. The authority citation for part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371; 42 U.S.C. 243, 264, 271.

§ 101.4 [Amended]

2. In § 101.4(h) introductory text and (h)(2), remove "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039" and, in its place, add "Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday".

§ 101.9 [Amended]

3. Amend § 101.9 by:

a. In paragraph (b)(7)(vi), removing "Office of Nutritional Products, Labeling and Dietary Supplements (HFS-800)" and, in its place, adding "Office of Nutrition and Food Labeling (HFS-800)";

b. In paragraph (c)(8)(iv), removing "2 microgram" and "dietary 24 micrograms dietary β-cryptoxanthin" in footnote 3 to the table and adding "2 micrograms" and "24 micrograms dietary β-cryptoxanthin" in their place, respectively;

c. In paragraph (d)(11)(iii), revising the sample label;

d. In paragraph (j)(5)(ii)(B), revising the sample label;

e. In paragraph (j)(13)(i) introductory text, adding a sentence at the end of the paragraph;

f. In paragraph (j)(13)(i)(B), removing "1-16 inches" and, in its place, adding "1/16 inches";

g. In paragraph (j)(13)(ii)(A)(*1*), revising the sample label;

h. In paragraph (j)(13)(ii)(A)(*2*), revising the sample label; and

i. In paragraph (j)(13)(ii)(B), revising the sentences that begin with "Total carbohydrate--Total carb", "Vitamin—Vit" and "Potassium—Potas".

The revisions read as follows:

§ 101.9

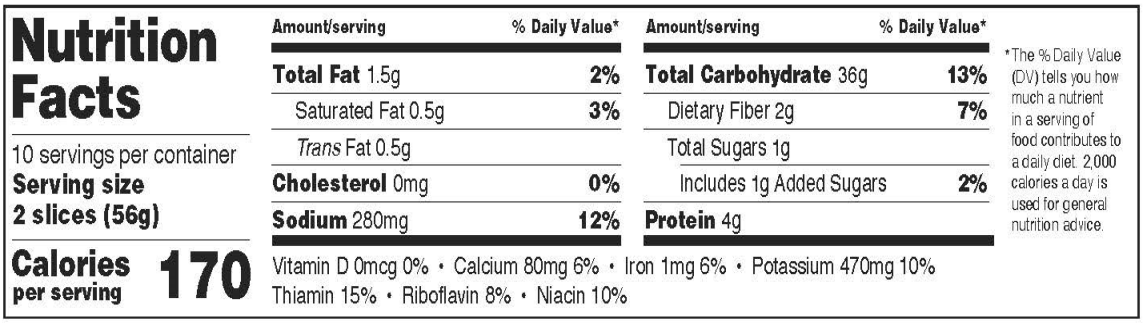
* * * * *

(d) * * *

(11) * * *

(iii) * * *

Tabular Format



Nutrition Facts

10 servings per container
Serving size
2 slices (56g)

Calories per serving **170**

Amount/serving	% Daily Value*
Total Fat 1.5g	**2%**
Saturated Fat 0.5g	**3%**
Trans Fat 0.5g	
Cholesterol 0mg	**0%**
Sodium 280mg	**12%**

Amount/serving	% Daily Value*
Total Carbohydrate 36g	**13%**
Dietary Fiber 2g	**7%**
Total Sugars 1g	
Includes 1g Added Sugars	**2%**
Protein 4g	

*The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Vitamin D 0mcg 0% • Calcium 80mg 6% • Iron 1mg 6% • Potassium 470mg 10%
Thiamin 15% • Riboflavin 8% • Niacin 10%

* * * * *

(j) * * *

(5) * * *

(ii) * * *

(B) * * *

Infants through 12 Months of Age

Nutrition Facts	
4 servings per container	
Serving size	**1 pack (70g)**
Amount per serving	
Calories	**25**
	% Daily Value
Total Fat 0g	**0%**
Saturated Fat 0g	
Trans Fat 0g	
Cholesterol 0mg	
Sodium 75mg	
Total Carbohydrate 5g	**5%**
Dietary Fiber 1g	
Total Sugars 3g	
Includes 0g Added Sugars	
Protein 0g	**0%**
Vitamin D 0mcg	0%
Calcium 10mg	4%
Iron 1mg	10%
Potassium 230mg	35%

* * * * *

(13) * * *

(i) * * * Foods in packages subject to requirements of paragraphs (j)(13)(ii)(A)(*1*) and (*2*) of this section do not require the information in paragraphs (d)(9) and (f)(5) related to the footnote, however the abbreviated footnote statement "% DV = % Daily Value" may be used.

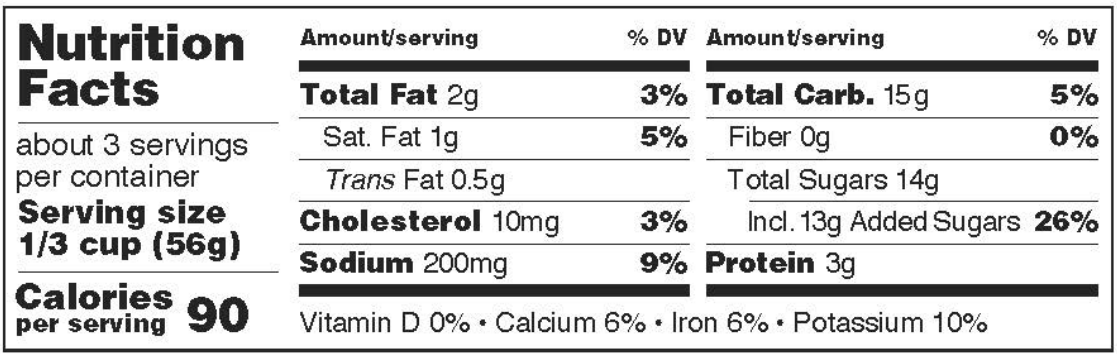
* * * * *

(ii) * * *

(A) * * *

(*1*) * * *

Tabular Display for Small Packages



Nutrition Facts

about 3 servings per container

Serving size 1/3 cup (56g)

Calories per serving 90

Amount/serving	% DV	Amount/serving	% DV
Total Fat 2g	**3%**	**Total Carb.** 15g	**5%**
Sat. Fat 1g	**5%**	Fiber 0g	**0%**
Trans Fat 0.5g		Total Sugars 14g	
Cholesterol 10mg	**3%**	Incl. 13g Added Sugars	**26%**
Sodium 200mg	**9%**	**Protein** 3g	

Vitamin D 0% • Calcium 6% • Iron 6% • Potassium 10%

(*2*) * * *

Linear Display for Small Packages

Nutrition Facts Servings: 12, **Serv. size: 1 mint (2g),**
Amount per serving: **Calories 5, Total Fat** 0g (0% DV), Sat. Fat 0g (0% DV), *Trans* Fat 0g, **Cholest.** 0mg (0% DV), **Sodium** 0mg (0% DV), **Total Carb.** 2g (1% DV), Fiber 0g (0% DV), Total Sugars 2g (Incl. 2g Added Sugars, 4% DV), **Protein** 0g, Vit. D (0% DV), Calcium (0% DV), Iron (0% DV), Potas. (6% DV).

(B) * * *

Total carbohydrate - Total carb. This abbreviation can also be used on dual-column displays as shown in paragraphs (e)(5), (e)(6)(i), and (e)(6)(ii) of this section.

* * * * *

Vitamin—Vit. This abbreviation can also be used on the standard vertical side-by-side display as shown in paragraph (d)(12) of this section.

Potassium—Pot. This abbreviation can also be used on the standard vertical side-by-side display as shown in paragraph (d)(12) of this section.

* * * * *

§ 101.45 [Amended]

4. Amend § 101.45 as follows:

a. In paragraph (b)(1) introductory text, remove "Office of Nutritional Products, Labeling and Dietary Supplements (HFS-800)" and, in its place, add "Office of Nutrition and Food Labeling (HFS-800)"; and

b. In paragraph (b)(1)(i), remove "FDA Office of Food Labeling" and, in its place, add "Office of Nutrition and Food Labeling (HFS-800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740".

§ 101.80 [Amended]

5. In § 101.80(c)(2)(iii)(C), remove "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039" and, in its place, add "Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday".

§ 101.81 [Amended]

6. In § 101.81(c)(2)(ii)(A) introductory text, (c)(2)(ii)(A)(*5*), (c)(2)(ii)(B)(*1)*, and (c)(2)(ii)(B)(*2)*, remove "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039" and, in its place, add "Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday".

§ 101.83 [Amended]

7. In § 101.83(c)(2)(ii)(A)(*2*) and (c)(2)(ii)(B)(*2)*, remove "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039" and, in its place, add "Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday".

§ 101.93 [Amended]

8. In § 101.93(a)(1), remove "Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810)" and, in its place, add "Office of Dietary Supplement Programs (HFS-810)".

§ 101.108 [Amended]

9. In § 101.108(c), remove "Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852" and, in its place, add "Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday".

PART 106--INFANT FORMULA REQUIREMENTS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS

10. The authority citation for part 106 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 350a, 371.

§ 106.150 [Amended]

11. In § 106.150(a)(1), remove "21 U.S.C 350d(i)" and, in its place, add "21 U.S.C. 350a(i)".

PART 170--FOOD ADDITIVES

12. The authority citation for part 170 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 346a, 348, 371.

§ 170.35 [Amended]

13. Amend § 170.35 as follows:

a. In paragraph (b)(1), remove "Division of Dockets Management" and, in its place, add "Dockets Management Staff"; and

b. In paragraph (b)(2), remove "Division of Dockets Management" and "Division of Dockets Management's office", and, in their place, add "Dockets Management Staff" and "Dockets Management Staff's office", respectively.

§ 170.38 [Amended]

14. Amend § 170.38 as follows:

a. In paragraph (b)(1), remove "Division of Dockets Management" and, in its place, add "Dockets Management Staff"; and

b. In paragraph (b)(2), remove "Division of Dockets Management" and "Division of Dockets Management's office" and, in their place, add "Dockets Management Staff" and "Dockets Management Staff's office", respectively.

§ 170.39 [Amended]

15. Amend § 170.39 as follows:

a. In paragraph (d), remove "Office of Premarket Approval" and, in its place, add "Office of Food Additive Safety";

b. In paragraph (e), remove "Division of Dockets Management" wherever it appears and, in its place, add "Dockets Management Staff" and remove "Office of Premarket Approval" in the sixth sentence and, in its place, add "Office of Food Additive Safety";

c. In paragraph (g), remove "Division of Dockets Management" in the fifth sentence and, in its place, add "Dockets Management Staff"; and

d. In paragraph (h), remove "Office of Premarket Approval" in the first sentence and, in its place, add "Office of Food Additive Safety".

PART 172--FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

16. The authority citation for part 172 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 348, 371, 379e.

§ 172.105 [Amended]

17. In § 172.105(b)(1), (2), and (3), remove "Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740" where it appears and, in its place, add "Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1200".

§ 172.133 [Amended]

18. In § 172.133(a)(2), remove "Center for Food Safety and Applied Nutrition (HFS-200), 5001 Campus Dr., College Park, MD 20740" and, in its place, add "Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1200".

§ 172.155 [Amended]

19. In § 172.155(c), in the third sentence, remove "Division of Product Policy (HFS-206), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740" and, in its place, add "Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1200" and remove "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039" and, in its place, add "Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday".

§ 172.167 [Amended]

20. Amend § 172.167 as follows:

a. In paragraph (b), remove "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039" and, in its place, add "Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers

Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday"; and

b. In paragraph (d)(2), remove "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, 301-436-2163", and, in its place, add "Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday"

§ 172.185 [Amended]

21. In § 172.185(b), remove "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039" and, in its place, add "Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday".

§ 172.250 [Amended]

22. In § 172.250(b)(3) footnote 1, remove "Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740" and, in its place, add "Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1200".

§ 172.320 [Amended]

23. Amend § 172.320 as follows:

a. In paragraph (g) introductory text, remove "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039" and, in its place, add "Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday"; and

b. In paragraph (g)(2), remove "FDA Main Library, 10903 New Hampshire Ave., Silver Spring, MD 20993" and, in its place, add "Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday".

§ 172.345 [Amended]

24. In § 172.345(b), remove "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039" and, in its place, add "Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday".

§ 172.379 [Amended]

25. In § 172.379(b), remove "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039" and, in its place, add "Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday".

§ 172.380 [Amended]

26. In § 172.380(b), remove "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039" and, in its place, add "Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday".

§ 172.665 [Amended]

27. In § 172.665(d)(2), remove "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039" and, in its place, add "Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers

Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday".

§ 172.712 [Amended]

28. In § 172.712(b), remove "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039" and, in its place, add "Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday".

§ 172.723 [Amended]

29. Amend § 172.723 as follows:

a. In paragraph (b)(1), remove "Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1200" and, in its place, add "Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday";

b. In paragraph (b)(3), remove "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039" and, in its place, add "Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday".

§ 172.736 [Amended]

30. Amend § 172.736 as follows:

a. In paragraph (b)(1), remove "Office of Food Additive Safety, 5001 Campus Dr., College Park, MD 20740" and, in its place, add "Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1200"; and

b. In paragraph (b)(1), (2), and (3), remove "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039" and, in its place, add "Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday".

§ 172.780 [Amended]

31. In § 172.780(b), remove "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039" and, in its place, add "Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday".

§ 172.785 [Amended]

32. In § 172.785(b)(1), remove "Office of Food Additive Safety (HFS-200), Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039" and, in its place, add "Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1200" and remove "Center for Food Safety and Applied Nutrition's Library, 5001 Campus Dr., College Park MD 20740" and, in its place, add "Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday".

§ 172.800 [Amended]

33. Amend § 172.800 as follows:

a. In paragraph (b)(1), remove "Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740" and, in its place, add "Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied

Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1200"; and

b. In paragraph (b)(2), remove "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039" and, in its place, add "Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday".

§ 172.803 [Amended]

34. In § 172.803(b) introductory text, remove "Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, 5001 Campus Dr., College Park, MD 20740" and, in its place, add "Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1200" and remove "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039" and, in its place, add "Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday".

§ 172.804 [Amended]

35. Amend § 172.804 as follows:

a. In the introductory text, remove "of the act" and, in its place, add "of the Federal Food, Drug, and Cosmetic Act";

b. In paragraph (b), remove "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039" and, in its place, add "Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday"; and

c. In paragraph (c)(2), remove “Office of Premarket Approval (HFS-200), Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039” and, in its place, add “Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1200”, and remove “Center for Food Safety and Applied Nutrition’s Library, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740” and, in its place, add “Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday”.

§ 172.809 [Amended]

36. In § 172.809(b), remove “Office of Food Additive Safety (HFS-200), Food and Drug Administration’s Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, 240-402-1200” and, in its place, add “Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1200” and remove “Center for Food Safety and Applied Nutrition’s Library, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740” and, in its place, add “Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday”.

§ 172.810 [Amended]

37. In § 172.810, in the introductory paragraph, remove “Food and Drug Administration’s Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039” and, in its place, add “Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday”.

§ 172.812 [Amended]

38. In § 172.812(a), remove "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039" and, in its place, add "Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday".

§ 172.829 [Amended]

39. In § 172.829(b) introductory text, remove "Office of Food Additive Safety (HFS-200), Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039" and, in its place, add "Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1200" and remove "Center for Food Safety and Applied Nutrition's Library, 5001 Campus Dr., rm. 1C-100, College Park, MD 20740" and, in its place, add "Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday".

§ 172.831 [Amended]

40. In § 172.831(b), remove "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039" and, in its place, add "Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday".

§ 172.833 [Amended]

41. Amend § 172.833 as follows:

a. In paragraph (b)(2), remove "Office of Food Additive Safety (HFS-200), Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, 240-402-1200" and, in its place, add "Office of Food

Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1200" and remove "Center for Food Safety and Applied Nutrition's Library, 5001 Campus Dr., College Park, MD 20740" and, in its place, add "Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday"; and

b. In paragraph (b)(4), remove "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039" and, in its place, add "Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday".

§ 172.841 [Amended]

42. In § 172.841(b), remove "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039" and, in its place, add "Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday".

§ 172.859 [Amended]

43. In § 172.859, remove "Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740" wherever it appears and, in its place, add "Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1200".

§ 172.862 [Amended]

44. In § 172.862(b)(1), remove "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039" and, in its

place, add “Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday”.

§ 172.864 [Amended]

45. Amend § 172.864 as follows:

a. In paragraph (a)(3), remove “Office of Food Additive Safety, 5001 Campus Dr., College Park, MD 20740” and, in its place, add “Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1200” and remove “Food and Drug Administration’s Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039” and, in its place, add “Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday”; and

b. In paragraph (b)(3) footnote 1, remove “Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740” and, in its place, add “Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1200”.

§ 172.867 [Amended]

46. In § 172.867(b), remove “Food and Drug Administration’s Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039” and, in its place, add “Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday”.

47. In § 172.869, revise the fourth sentence of paragraph (b) introductory text and paragraph (b)(1) to read as follows:

§ 172.869 Sucrose oligoesters.

* * * * *

(b) * * *Copies may be examined at the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday, or at the National Archives and Records Administration (NARA).* * *

Specification	Limit	Method Cited	Source for Obtaining Method
(1) Sucrose esters	Not less than 90%	"Method for Analyzing the Purity of Sucrose Fatty Acid Esters," Chemical Corp., June 17, 1998.	Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1200.
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§ 172.878 [Amended]

48. In § 172.878(a)(3), remove "Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740" and, in its place, add "Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1200".

§ 172.882 [Amended]

49. In § 172.882(a), remove "Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740" and, in its place, add "Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1200".

§ 172.886 [Amended]

50. Amend § 172.886 as follows:

a. In paragraph (b) footnote 1, remove "Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740" and, in its place, add "Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1200"; and

b. In paragraph (c)(2)(iii), remove "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039" and, in its place, add "Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday".

PART 173--SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

51. The authority citation for part 173 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

§ 173.25 [Amended]

52. In § 173.25(b)(2)(ii)(B), remove "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039" and, in its place, add "Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday".

§ 173.45 [Amended]

53. In § 173.45(a), remove "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039" and, in its place, add "Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers

Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday".

§ 173.60 [Amended]

54. In § 173.60(b)(3), remove "Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740" and, in its place, add "Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1200".

§ 173.65 [Amended]

55. In § 173.65(b), remove "Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740" and, in its place, add "Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1200".

§ 173.73 [Amended]

56. In § 173.73(a)(2), remove "Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740" and, in its place, add "Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1200".

§ 173.115 [Amended]

57. In § 173.115(b)(3), remove "Center for Food Safety and Applied Nutrition, 5001 Campus Dr., College Park, MD 20740" and, in its place, add "Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday".

§ 173.160 [Amended]

58. Amend § 173.160 as follows:

a. In paragraph (b)(2), remove "Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740" and, in its

place, add “Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1200”; and

b. In paragraph (d), remove “Food and Drug Administration’s Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039” and, in its place, add “Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday”.

§ 173.165 [Amended]

59. Amend § 173.165 as follows:

a. In paragraph (b)(2), remove “Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740” and, in its place, add “Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1200”; and

b. In paragraph (d), remove “Food and Drug Administration’s Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039” and, in its place, add “Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday”.

§ 173.228 [Amended]

60. In § 173.228(a), remove “Food and Drug Administration’s Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039” and, in its place, add “Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday”.

§ 173.280 [Amended]

61. In § 173.280(c), remove "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039" and, in its place, add "Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday".

§ 173.300 [Amended]

62. In § 173.300(a)(2), add ", 240-402-1200" after "Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740" and remove "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20994, 301-796-2039" and, in its place, add "Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday".

§ 173.310 [Amended]

63. Amend § 173.310 as follows:

a. In paragraph (f) introductory text, remove "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039" and, in its place, add "Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday"; and

b. In paragraph (f)(1), remove "FDA Main Library, 10903 New Hampshire Ave., Silver Spring, MD 20993" and, in its place, add "Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday".

§ 173.325 [Amended]

64. In § 173.325(h), remove "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039" and, in its place, add "Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday".

65. In § 173.340, in the table to paragraph (a)(4), revise the entry for "*n*-Butoxypoly(oxyethylene)-poly(oxypropylene)glycol" to read as follows:

§ 173.340 Defoaming agents.

* * * * *

(a) * * *

(4) * * *

Substances	Limitations
n-Butoxypoly(oxyethylene)-poly(oxypropylene) glycol	Viscosity range, 4,850-5,350 Saybolt Universal Seconds (SUS) at 37.8 °C (100 °F). The viscosity range is determined by the method "Viscosity Determination of *n*-butoxypoly(oxyethylene)-poly(oxypropylene) glycol" dated April 26, 1995, developed by Union Carbide Corp., P.O. Box 670, Bound Brook, NJ 08805, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of the material incorporated by reference are available from the Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1200, and may be examined at the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: https://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.
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§ 173.356 [Amended]

66. In § 173.356(a), remove "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039" and, in its

place, add “Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday”.

67. In § 173.357, in the table to paragraph (a)(2), revise the entry for “Polyethylenimine reaction product with 1,2-dichloroethane (CAS Reg. No. 68130-97-2)” to read as follows:

§ 173.357 Materials used as fixing agents in the immobilization of enzyme preparations.

* * * * *

(a) * * *

(2) * * *

Substances	Limitations
* * * * * * *	
Polyethylenimine reaction product with 1,2-dichloroethane (CAS Reg. No. 68130-97-2) is the reaction product of homopolymerization of ethylenimine in aqueous hydrochloric acid at 100 °C and of cross-linking with 1,2-dichloroethane. The finished polymer has an average molecular weight of 50,000 to 70,000 as determined by gel permeation chromatography. The analytical method is entitled “Methodology for Molecular Weight Detection of Polyethylenimine,” which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, 5001 Campus Dr., College Park, MD 20740, 240-402-1200, and may be examined at the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*	May be used as a fixing material in the immobilization of glucoamylase enzyme preparations from *Aspergillus niger* for use in the manufacture of beer. May be used as a fixing material in the immobilization of: 1. Glucose isomerase enzyme preparations for use in the manufacture of high fructose corn syrup, in accordance with § 184.1372 of this chapter. 2. Glucoamylase enzyme preparations from *Aspergillus niger* for use in the manufacture of beer. Residual ethylenimine in the finished polyethylenimine polymer will be less than 1 part per million as determined by gas chromatography-mass spectrometry. The residual ethylenimine is determined by an analytical method entitled “Methodology for Ethylenimine Detection in Polyethylenimine,” which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Residual 1,2-dichloroethane in the finished polyethylenimine polymer will be less than 1 part per million as determined by gas chromatography. The residual 1,2-dichloroethane is determined by an analytical method entitled, “Methodology for Ethylenedichloride Detection in Polyethylenimine,” which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be

	obtained from the Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, 5001 Campus Dr., College Park, MD 20740, 240-402-7500, or may be examined at the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*
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§ 173.368 [Amended]

68. In § 173.368(c), remove "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039" and, in its place, add "Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday".

§ 173.370 [Amended]

69. In § 173.370(c), remove "Division of Petition Review, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740" and, in its place, add "Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1200" and remove "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039" and, in its place add "Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane,

rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday".

§ 173.375 [Amended]

70. In § 173.375(a), remove "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039" and, in its place, add "Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday".

§ 173.400 [Amended]

71. In § 173.400(b) and (c)(2)(ii), remove "Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740", and in its place add "Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1200".

PART 184--DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

72. The authority citation for part 184 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 371.

PART 184 [AMENDED]

73. In part 184, remove "Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039" wherever it appears and, in its place, add "Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday".

§ 184.1538 [Amended]

74. Amend § 184.1538 as follows:

a. In paragraph (b) introductory text, remove "Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852" and, in its place, add "Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday"; and

b. In paragraph (d), remove "Division of Dockets Management (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857" and, in its place, add "Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday".

PART 190--DIETARY SUPPLEMENTS

75. The authority citation for part 190 continues to read as follows:

Authority: Secs. 201(ff), 301, 402, 413, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(ff), 331, 342, 350b, 371).

§ 190.6 [Amended]

76. In § 190.6(a), remove "Office of Nutritional Products, Labeling and Dietary Supplements (HFS-820), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740" and, in its place, add "Office of Dietary Supplement Programs (HFS-810), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740".

Dated: March 13, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-05418 Filed: 3/23/2023 8:45 am; Publication Date: 3/24/2023]